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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,746	FERNANDEZ-SALAS ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-20,22,45-47,56 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-20,22,45-47,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/08 has been entered.

Status of Application/Amendments/claims

2. Applicant's amendment filed 2/25/08 is acknowledged. Claims 2, 21 and 48-55 are cancelled. Claims 1, 3-20, 22, 45-47 and 56-57 are pending in this application and under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on 2/25/08 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

5. The objection to specification is maintained because the specification fails to point to specific portions of the referenced document where the subject matter being

incorporated may be found and also fails to indicate the relationship between the instant application and the cited applications.

At p. 10-12 of the response, Applicant argues that the recitation of US aplication 10/757077as incopoarted by reference is appropriate and cites Ex parte Harvey and In re Fouche in support of the arguments. Applicant's arguments have been fully considered but they are persuasive.

In response, although MPEP 608.01(p) permits applicant to fill in a number of a copending application no. that has an attorney docket no. described in the specification, the incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

In this case, Applicant is required to include the essential material (i.e. observing about 20-300% more BoNT/A light chain location to the plasma membrane as recited in instant claims 3, 46 and observing about 10-90% reduction in plasma membrane location of the BoNT/A light chain as it recited in instant claims 4 and 47) in the disclosure.

At p. 13 of the response, Applicant argues that the examiner misapplied the law because the question is whether 10/757077 was improperly incorporated by reference.

In response, the examiner acknowledged that the recitition of 10/757077 is permitted. However, the specification fails to indicate the relationship between the instant application and the cited applications because the claimed benefit under 35 U.S.C 120 may not be considered. See MPEP 201.11 (III).

"The third requirement of the statute is that the later-filed application must contain a specific reference to the prior application. This should appear as the first sentence(s) of the specification following the title preferably as a separate paragraph (37 CFR 1.78(a)) and/or in an application data sheet (37 CFR 1.76).".

"Any benefit claim that does not both identify a prior application by its application number and specify a relationship between the applications will not be considered to contain a specific reference to a prior application as required by 35 U.S.C. 120. Such benefit claim may not be recognized by the Office and may not be included on the filing receipt even if the claim appears in the first sentence(s) of the specification or an application data sheet. As a result, publication of the application may not be scheduled as a function of the prior application's filing date. If the Office does not recognize a benefit claim under 35 U.S.C. 120 because it does not contain the required reference and the time period set forth in 37 CFR 1.78(a)(2)(ii) for submitting the required reference has expired, applicant must submit a petition under 37 CFR 1.78(a)(3) and the surcharge set forth in 37 CFR 1.17(t) in order for the Office to accept the unintentionally delayed claim under 35 U.S.C. 120 since the application will not have been scheduled for publication on the basis of the prior application's filing date". See MPEP 201.11 (III).

Claim Rejections/Objections Maintained

In view of the amendment filed on 2/25/08, the following rejections are maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 46 and 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The rejection is maintained for the reasons made of record in the office actions mailed 3/29/07 & 7/23/07, and as follows.

At p.14-20 of the response, Applicant argues that claims 3, 4, 46 and 47 meet the written description requirement because the limitations “about 20% to about 300% increase” and “about 10% to about 90% reduction" are described in the present specification. Applicant argues that the specification provides sufficient detail as to conclude Applicant’s possession of the claimed invention and because the specification incorporated by reference 10/757077, a continuation-in-part of US application 10/163106 filed June 4, 2002. Applicant’s arguments have been fully considered but they are persuasive.

In contrast, the instant specification fails to disclose a method of screening for a compound that increases *about 20% to about 300% more* of the BoNT/A light chain on the plasma membrane as recited in instant claims 3 and 46, and a method of screening for a compound that decreases *about 10% to about 90% reduction* of the BoNT/A light chain on the plasma membrane as recited in instant claims 4 and 47. Although the specification of 10757077 discloses a modified neurotoxin with a reduced biological persistence wherein the biological persistence is reduced by about 10% to about 90%

or is increasd by about 20% to about 300% (see [0109] & [0156] of the specification of 10/757077), the specification fails to disclose use of different percentages of increase or reduction of the BoNT/A light chain in a method of screening for test a compound to reduce or increase of the BoNT/A light chain on the plasma membrane. The inventive concept which is now claimed does not flow from the disclosure of the % increases/decreases for the modified neurotoxin. In addition, the instant specification also fails to disclose such screening method for a compound by that increases biological persistence of BoNT/A light chain by observing about 20%-about 300% more BoNT/A light chain localized to the plasma membrane or that decreases biological persistence of BoNT/A light chain by observing about 10% to about 300% less BoNT/A light chain localized to the plasma membrnae. The instant specification only discloses

"the density of the light chain of toxin type A that is localized to the plasma membrane is reduced by more than about 20%, preferably more than about 40%, more preferably more than about 60%, for example 80%" (see p. 31 of the specification).

Thus, the specification fails to disclose the limitations of "a method of detecting different percentages of increase or reduction of the BoNT/A light chain on the plasma membrane by a test compound" as recited in instant claims.

In addition, as evidenced by the instant specification (see p.1) and the response (p.11), the instant disclosure is a continuation-in-part of 10/757077 filed Jan 14, 2004. The limitations of observing different percentages of decrease or increase of BoNT/A light chain on the plasma membrane in a screening method to identify a test compound that decreases or increases BoNT/A light chain location on the plasma membrane are new matter because neither the instant specification nor the specification of 10/757077

or other prior copending applications disclose such limitations. Accordingly, the rejection of lack of written description requirement due to new matter is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-20, 22, 45-47, 56 and 57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6762280 (Schmidt et al. issued on Jul 13, 2004, effective filing date Sep 25, 2000) in view of Fernandez-Salas et al. (Society for Neuroscience Abstract Viewer and Itinerary Planner, 2003. Vol 2003, pp. Abstract No. 9.2.) or Fernandez-Salas et al. (Steward et al. Naunyn-Schmiedeberg's Archives of Pharmacology, June 2002. Vol. 365 No. Supplement 2, pp. R19). The rejection is maintained for the reasons made of record in the office actions mailed 3/29/07 & 7/23/07, and as follows.

At p. 21-24 of the response, Applicant argues that the examiner incorrectly equated biological persistence as proteolytic activity and failed to identify the limitation of a compound that alters biological persistence by observing BoNT/A plasma membrane location patterns because biological persistence and proteolytic activity are distinct from each other. Applicant argues that Schmidt teaches a method of screening for a compound that reduces/increases BoNT/A proteolytic activity not biological

persistence of BoNT/A. Applicant argues that neither Fernandez-Salas I and Fernandez-Salas II abstract discloses the above limitations instead they support that biological persistence and proteolytic activity of BoNT/A are distinct. Applicant's arguments have been fully considered but they are persuasive.

In response, in contrast to Appellant's arguments, the examiner asserts that the examiner did not incorrectly equate the biological persistence of BoNTA as proteolytic activity or neurotoxicity of BoNT/A. Rather the examiner reasoned that the claimed BoNT/A is obvious over the applied references based on the scientific rationale that the biological persistence of BoNT/A depends on the proteolytic activity of the light chain of BoNT/A. As previously made of record, the biological activity or neurotoxicity of BoNT/A is based on and determined by the proteolytic activity of the light chain of BoNT/A to cleave SNAP25 or other synaptic proteins, which is the process of inhibiting exocytosis of synaptic vesicles. The process of inhibiting exocytosis encompasses and is accompanied with the time that the BoNT/A light chain inhibits the exocytosis of neurotransmitter because the biochemical process requires time to process. In addition, the instant specification defines "Biological persistence" as "is meant to refer to the continuous period of time that a light chain retains its enzymatic activity when that light chain is within a cell or outside of a cell (see p. 10 the instant specification). Therefore, the biological persistence is not distinct from proteolytic activity because it is an inherent or intrinsic feature of the process of inhibition of exocytosis of neurotransmitter by the BoNT/A light chain, which is required by the process of proteolysis and the process of inhibition of exocytosis to occur. Regardless of the length of the time of the inhibition,

the time required to execute the proteolytic activity is an inherent or intrinsic feature or biochemical property of the BoNT/A light chain. Thus, the duration of inhibition of exocytosis would be also an inherent or intrinsic biochemical property of the light chain or modified light chain of BoNT/A and is determined by the proteolytic activity of the light chain. Once the proteolytic activity is reduced, the biological activity and biological persistence of BoNT/A would consequently be reduced.

At p. 26-30 of the response, Applicant argues that the examiner failed to identify the limitation of a compound that alters biological persistence by observing BoNT/A plasma membrane localization pattern relative to a control. Applicant argues that BoNT/A biological persistence is controlled by light chain localization to the plasma membrane and is independent from whether the light chain can cleave SNAP25 and SNAP25 cleavage occurs intracellularly is immaterial to the claimed limitation of observing and comparing light chain membrane localization pattern in order to determine altered BoNT/A biological persistence. Applicant's arguments have been fully considered but they are persuasive.

In response, Applicant's arguments with regard to biological persistence have been answered as set forth above. Applicant's argument that the biological persistence of BoNT/A is independent from the proteolytic activity of the light chain to cleave SNAP25 is incorrect. In addition, Applicant erroneously states that the examiner asserts that cleavage of SNAP25 by BoNT/A triggers endocytosis of the complex. The examiner only states that BoNT/A is endocytosed into intracellular domain of the cell, the light

chain of BoNT/A will be separated from the heavy chain and further to cleave the substrates such as SNAP 25 on the neuronal plasma membrane or other synaptic proteins on synaptic vesicles. The cleavage of SNAP25 or other synaptic proteins by the light chain of BoNT/A is a process of proteolysis (i.e. proteolytic activity of the light chain) and it is the key of the biological activity (i.e. neurotoxicity) of BoNT/A. Once the light chain of BoNT/A proteolyses SNAP25 or other synaptic proteins, the synaptic vesicles containing neurotransmitters (such as ACh) cannot be docketed to the neuronal plasma membrane to execute the step of exocytosis of synaptic vesicles (synaptic transmission). In addition, as acknowledge by Applicant, the cleavage of SNAP25 or other synaptic proteins related to synaptic vesicles are dependent on the BoNT/A light chain and SNAP25 or other synaptic proteins involved in the proteolytic activity of BoNT/A light chain are localized on the plasma membrane. Thus, the localization of BoNT/A light chain in the claimed method is highly associated with the proteolytic activity of BoNT/A and its substrates on the plasma membrane such as SNAP25.

At p. 32-38 of the response, Applicant argues that the combined references would not render the claimed invention obvious because there was no motivation or suggestion to do so. At p. 48-51, Applicant argues that the combined references do not provide an expectation of success. Applicant's arguments have been fully considered but they are persuasive.

In response, Applicant's arguments with regard to biological persistence have been answered as set forth above.

In response, the motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. MPEP. §2144.07.

In addition, it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In contrast, the applied references do teach the claimed method. Schmidt (US Patent No. 6762280) teaches a method for identifying a compound that either inhibits or enhances the proteolytic activity of botulinum neurotoxin serotype A (BoNT/A). Although Schmidt does not use a cell-based screening system for the screening steps, the references of Fernandez-Salas et al. I/II teach the steps of the screening method using the cell-based system by a fusion protein of the BoNT/A light chain to GFP protein and confocal microscopy to detect the colocalization of GFP-BoNT/A light chain with transfected SNAP25 in neurons. Thus, the claimed method is obvious over the teachings of Schmidt et al. (US Patent No. 6762280, Fernandez-Salas et al. (I) and (II).

In addition, the combined references do provide a motivation and expectation of success. Although, Schmidt teaches different methods of identifying proteolytic activity of BoNT/A, the biological persistence of BoNT/A relies on the proteolytic activity of the light chain of BoNT/A to inhibit neurotransmitter release. Accordingly, affecting

proteolytic activity of the light chain of BoNT/A would consequently affect the biological persistence of BoNT/A. Thus, the teachings of 'Schmidt provide a motivation and expectation of success in screening for a compound that reduces/increases the biological persistence of BoNT/A by affecting the proteolytic activity of BoNT/A light chain on SNAP25 or other substrates of SNARE proteins since affecting proteolytic activity of the light chain would consequently affect the biological persistence of BoNT/A.

Although Schmidt does not use the cell-based screening system as in the screening steps, the references of Fernandez-Salas et al. I/II provide the steps of the screening method using cell based system because the references teach that the fusion protein of the light chain of BoNT/A to GFP protein is colocalized with SNAP25 after transfected in neurons and the colocalization can be detected by confocal microscopy. The combined teachings of Schmidt et al. and Fernandez-Salas et al. provide a motivation and expectation of success in observing the change of localization of light chain of BoNT/A since cleavage of SNAP25 occurs in an intracellular compartment of the plasma membrane and the localization of BoNT/A light chain on the plasma membrane also dependent on the substrate on the plasmas membrane cleaved by the BoNT/A light chain. A skilled artisan would have been motivated and have reasonable expectations of success in combining the teachings of Schmidt et al. (US Patent No. 6762280) and Fernadez-Salas et al.I/II to screen a compound that affects a biological persistence of a Clostridial toxin by evaluating the localization and enzymatic activity of

BoNT/A since the biological persistence of BoNT/A relies on the proteolytic activity of the light chain. Note that

"Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)" See MPEP § 2143. 01-I.

"The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.,* 325 U.S. 327, 65 USPQ 297 (1945)". See MPEP 2144.07.

In addition, the recitation of ranges of about 20-300% increase or 10-90% decrease in claims 3, 4, 46, 47, 56 and 57 is routine optimization, which does not render the claimed invention patentable. Note that

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).Even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 CCPA (Patents) 1313, 77 F.2d 627, 25 USPQ 433; In re Normann et al., 32 CCPA (Patents) 1248, 150 F.2d 627, 66 USPQ 308; In re Irmscher, 32 CCPA (Patents) 1259, 150 F.2d 705, 66 USPQ 314.

Further, these limitations are in a "wherein clause" for the intended results of the modification of the BoNT/A light chain, which the court held unpatentable. Note that

"In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id.* However, the court noted (quoting *Minton v.Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "'whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" *Id.*< See MPEP § 2111.04.

At p. 38-45 of the response, Applicant argues that the combined references make the Schmidt patent unsatisfactory for its intended use and change the operation of the Schmidt patent. At p. 45-48 of the response, Applicant argues that the combined references solved different problems of the Schmidt. Applicant's arguments have been fully considered but they are persuasive.

In response to applicant's argument related to different use and operation of the Schmidt patent, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In contrast to Applicant's assertion, the arguments with respect to the problems solved by the applied references are different from the use of the Schmidt patent are irrelevant to the patentability because as the prior art teaches the claimed method or render the claimed method obvious, it is irrelevant as to how the problems solved by the Schmidt patent are different from the applied references.

Conclusion

8. NO CLAIM IS ALLOWED.

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
April 24, 2008

/Christine J Saoud/
Primary Examiner, Art Unit 1647